FINAL REPORT OF PRELIMINARY FINDINGS AND RECOMMENDATIONS

By the

Phlebotomy Services Technical Committee for the

Review of the Application on

Phlebotomy Services by the

Nebraska Hospital Association

To the

Nebraska Board of Health,

Director of Health,

and the

Nebraska Legislature

October 28, 1991

LIST OF COMMITTEE MEMBERS

The members appointed by the Director of Health to serve on the Phlebotomy Services Technical Review Committee are as follows:

Charles Wempe, D.V.M., Chairperson (York)

Linda Ament, R.N., President of NAHCHA, Director, Beatrice Community Hospital Home Health Agency, (Beatrice)

Judith C. Dull, R.N., Coordinator, Health/Allied Health, Metropolitan Community College (Omaha)

Donald A. Dynek, M.D., Pathologist, Pathology Medical Services (Lincoln)

Marcy Wyrens, R.R.T., Supervisor, Respiratory Care Services, Lincoln General Hospital (Lincoln)

John O. Gradwohl, Community Analyst, Northeast Nebraska Economic Development District (Laurel)

John Roberts, Director of Policy Development, Nebraska Hospital Association (Lincoln)

VOLUNTARY CONSULTANTS TO THE COMMITTEE

Gaye Homer, MT-ASCP, University of Nebraska-Lincoln, Health Center (Lincoln)

Daniel Thorne, MT-ASCP, Pathology Medical Services (Lincoln)

INTRODUCTION

The Nebraska Credentialing Review Program which was established by the Nebraska Regulation of Health Professions Act in 1985 is a review process advisory to the Legislature, and is designed to assess the necessity of state regulation of health professions based upon criteria that require the examination of proposals for credentialing or changes in scope of practice from the standpoint of whether such proposals are necessary for the protection of public health, safety, or welfare.

The law directs those health occupations seeking credentialing or a change in scope of practice to submit an application for review to the Director of Health. At that time, an appropriate technical committee is formed to review the application and make recommendations after a public hearing is held. The recommendations are to be made on whether the health occupation should be credentialed according to the four criteria contained within Section 71-6221 Nebraska Revised Statutes; and if credentialing is necessary, at what level. The relevant materials and recommendations adopted by the technical committee are then sent to the Board of Health and the Director of Health for their review and recommendation. All recommendations are then forwarded to the Legislature.

SUMMARY OF COMMITTEE CONCLUSIONS AND RECOMMENDATIONS

The members of the technical committee at the request of the applicant group tabled the applicant's original proposal which called for indirect regulation of phlebotomy through the state's lab certification and hospital licensure program. The committee members then approved a motion to recommend the following course of action to subsequent review bodies regarding the practice of phlebotomy in Nebraska:

> . . .that the practice of phlebotomy be exempted from the Medical Practice Act. Specifically, we recommend that Nebraska Revised Statute 71-1,103 be amended to add to the list of persons who are excepted from the definition of the unauthorized practice of medicine. We concur with the Nebraska Medical Association that the language [that would accomplish this] should be reflected as follows: ". . . persons obtaining blood specimens while working under the direction of a physician or registered nurse." (Memorandum to the technical committee from John Roberts of the NHA, September 30, 1991)

The committee members also adopted a motion that would apply this exemption to all DWI cases wherein blood samples are taken for the purpose of ascertaining blood alcohol levels.

SUMMARY OF THE ORIGINAL APPLICANT PROPOSAL

The original proposal called for the regulation of phlebotomy services under the Nebraska Clinical Laboratories Certification Act, and through hospital licensure statutes. Under this proposal, the drawing of blood would be restricted to individuals who have completed a specific amount of minimal training provided by their employer under rules and regulations developed by the Department of Health, and who have demonstrated a defined minimal competence based upon this training. Practice for each practitioner would be limited to the facility wherein training was received, except that once training has been received and documented, the practice could be portable from one regulated facility to another.

Minimum training would include five clock hours of didactic training carried out under the general supervision of a licensed physician or surgeon or clinical laboratory director, and would include instruction and demonstration regarding the following procedures and functions:

pertinent anatomy and physiology
choice of equipment
proper technique
care of specimen
hazards and complications
post puncture patient care

The trainee would also be required to demonstrate proficiency in at least three venipunctures, three skin punctures, and three arterial punctures. (Page four of the Applicants' Proposal.)

SUMMARY OF THE ISSUES RAISED BY THE ORIGINAL PROPOSAL

Background

The original proposal submitted by the Nebraska Hospital Association was developed in response to a ruling by the Attorney General of the state of Nebraska which interprets Nebraska statutes as limiting the drawing of blood to the following five health professions: medical doctors, registered nurses, physician assistants, those LPNs with the appropriate educational background, and emergency medical technician-paramedics. (Memorandum from Robert M. Spire, Attorney General, State of Nebraska, October 2, 1990.)

This ruling stated that the Department of Health does not have the authority to develop rules and regulations to define what constitutes a "qualified technician"in the area of phlebotomy for DWI purposes, and therefore cannot use rules and regulations to extend the right to provide phlebotomy services to unlicensed auxiliary personnel.

The ruling stated that statute 39-669.14 does not authorize unlicensed persons to draw blood, and that this act is essentially part of the practice of medicine and surgery.

The ruling further stated that the pertinent statute (71-1,103) makes no exception for "qualified technicians" per se, but that there are exceptions for those professions who are licensed in the fields listed above. (Memorandum from Robert M. Spire, Attorney General, State of Nebraska, October 2, 1990.)

The events leading up to this ruling began in Fillmore County, wherein a court overturned the results of a blood test of a person suspected of a DWI offense because the individual who took the specimen did not clearly fit the definition of a "qualified technician" under Nebraska law. The Attorney General's ruling has implications which go far beyond DWI cases. If this

ruling were enforced by the Department of Health, thousands of health care employees in doctors' offices, clinics, and hospitals who are currently providing phlebotomy services would be prohibited from providing such services. This would severely restrict the availability of phlebotomy services to Nebraskans, especially rural and low-income Nebraskans.

Is There Harm to the Public in the Provision of Phlebotomy Services in Nebraska?

There is a consensus among the health care professionals who have participated in the review of this proposal that the public is not being harmed by the current practice situation of phlebotomy in Nebraska which is de facto an unregulated practice. Most phlebotomists work under the supervision of either an MD or an RN. No evidence of harm to the public vis-a-vis these services as currently provided was presented to the committee.

The committee understood, however, that there was the potential for harm to the public should the strict interpretation by the Attorney General be applied to the Nebraska health care system.

The committee members were informed that there is some potential for harm inherent in the provision of these services, and that in situations where phlebotomists practice without MD or RN supervision, actual harm to the public is possible. (Position Paper on Blood Drawing, Nebraska Department of Health, June 27, 1991.)

A testifier for the Nebraska Medical Association disagreed with those who perceived significant potential for harm from the drawing of blood from an existing access port. This testifier stated that there is little that is inherently more dangerous in this procedure than there is from routine venipuncture. He stated that the main reason for an access port in the first place is to preclude the necessity of repeated venipunctures, and that

there is no reason to be more concerned about this than about any other phlebotomy procedure. (Page 26 of the Transcript of the Public Hearing, September 4, 1991.)

Does the Proposal Adequately Address the Problems Identified by the Applicant Group?

There are two principal issues that the committee members addressed pertinent to this question. These are as follows:

1) What impact would the proposal have on phlebotomy services provided in physicians' offices and clinics not currently covered by the lab certification program of the Department of Health?

A testifier for the Nebraska Medical Association stated that the proposal, as he read it, would exclude any cite not qualifying as a laboratory facility under the terms of LB 551 (1991), and would therefore exclude many pharmacies, health fairs, and home health agencies. (Page 27 of the Transcript of the Public Hearing, September 4, 1991.)

A testifier from the Division of Health Promotion and Education of the Department of Health expressed the concern that the applicant's proposal would severely restrict access to phlebotomy services for low income families. This testifier stated that many clinics that currently provide these services would not meet the qualifications necessary to be covered under the lab certification program, and therefore would be excluded from providing services under the terms of the applicant's proposal. (Minutes of the Second Meeting of the Technical Committee, August 14, 1991.)

A testifier for the Nebraska AIDS Project expressed the concern that the proposal would have an adverse impact on alternative site testing. This testifier stated that the provision in the proposal

that would require training to be conducted within a formal institutional setting, and which would limit practice to institutions that meet the requirements for lab certification, would in effect exclude phlebotomy services at alternative sites. This testifier stated that persons who fear that they may have AIDS are reluctant to seek AIDS testing in such public facilities as hospitals because of the stigma associated with AIDS in the public mind. This is why these persons need to have access to the services provided by such alternative site testing programs as the Nebraska AIDS Project. This testifier was concerned that this access would in effect be denied by the applicant's proposal. (Pages 53-57 of the Transcript of the Public Hearing, September 4, 1991.)

The applicant group acknowledged that their proposal would exclude those phlebotomy services not covered by the lab certification process, and that in order to cover them under the terms of the proposal, the "umbrella" of the lab certification process would have to be expanded. (Minutes of the Second Meeting of the Technical Committee, August 14, 1991; and page 20 of the Transcript of the Public Hearing, September 4, 1991.) No specific proposal to accomplish this was advanced.

2) To what extent would the proposal address phlebotomy practice in institutions currently covered by the lab certification program?

A testifier from the Division of Health Facility Standards of the Department of Health stated that currently the proposal could not be implemented without making changes in the statute on laboratory certification. This testifier also stated that the proposal would require the development of a complete set of rules and regulations just for specimen collectors, and expressed concerns about how such rules and regulations would be enforced. This testifier stated that the

proposal would put the Department in the position of having to decertify a facility that failed to comply with the provisions of the five-hour training module. (Minutes of the Second Meeting of the Technical Committee, August 14, 1991.)

A medical technologist from the Pathology Center in Omaha expressed concerns about regulating phlebotomists, but stated that if some form of regulation is necessary that it be the least intrusive form of regulation, and that the proposal of the NHA for indirect regulation would be less burdensome than direct regulation via personnel standards. (Page 46 of the Transcript of the Public Hearing, September 4, 1991.)

A testifier for the Nebraska Society for Medical Technology stated that the proposal does not establish standardization of training for phlebotomists vis-a-vis the content of the training, and that the applicants have not clarified what, if any, additional practical training beyond the five hours of didactic training would be needed to perform the variety of functions associated with the provision of phlebotomy services. This testifier stated that the training program outlined in the proposal would be sufficient for capillary puncture, but not for arterial puncture. This testifier stated that arterial puncture is a skill that must be learned in a clinical situation where the phlebotomist learns by performing the procedure under direct supervision. (Page 32 of the Transcript of the Public Hearing, September 4, 1991.)

The committee members were informed that some phlebotomy procedures, such as those associated with drawing blood from an existing access port, require the administration of medications and special care functions, and were concerned that the amount of

preparation described in the proposal would not be sufficient to prepare a phlebotomist to perform such duties safely and effectively under such circumstances. (Minutes of the Second Meeting of the Technical Committee, August 14, 1991.)

The testifier from the Pathology Center in Omaha stated that this institution provides multiple levels of training for phlebotomists, and that the techniques that each phlebotomist uses are dictated by the institution. This testifier acknowledged that requiring multiple levels by law could be burdensome to many institutions. (Pages 45 and 46 of the Transcript of the Public Hearing, September 4, 1991.)

The testifier for the Nebraska Society for Medical Technology also stated that the proposal needs to clarify how phlebotomy is defined, since the definition has not kept up with changes in practice. This testifier stated that phlebotomy is no longer perceived as surgical cutting, and that doctors have been delegating this procedure to laboratory personnel and auxiliary personnel for over fifty years. This testifier stated that the practice needs to be defined in terms of the training received by personnel, rather than by the service provided. This testifier felt that this would be more consistent with the protection of public health and welfare. (Pages 33-35 of the Transcript of the Public Hearing, September 4, 1991.)

A testifier for the Nebraska Medical Association stated that phlebotomy should be defined in terms of the service provided rather than by the training. The testifier for the Pathology Center in Omaha agreed on this particular point. (Pages 25 and 43 of the Transcript of the Public Hearing, September 4, 1991.)

The testifier for the NSMT stated that the proposal also needs to

clarify the nature of the supervision that would be provided. This testifier stated that it is standard practice in laboratories for supervision to be "sample-controlled" which is a form of indirect supervision in which the supervisor examines the samples collected by the personnel he/she supervises. Under this method of supervision, appropriate standards pertinent to such things as tubes, proper volume of blood in the tubes, and hemolysis can be defined. This testifier felt that this would be the most effective method of supervision for phlebotomy personnel because it would be the most flexible method of supervision for them given the variety of procedures that they perform. (Page 33 of the Transcript of the Public Hearing, September 4, 1991.)

This testifier addressed the issue of grandfathering of phlebotomists by stating that any grandfathering should be based on the procedures that each phlebotomist has actually been trained to perform, rather than providing each phlebotomist with a blanket endorsement to provide all pertinent services regardless of training. (Pages 35 and 36 of the Transcript of the Public Hearing, September 4, 1991.)

The applicant group expressed support for some type of grandfathering for the reason that it would make it unnecessary for current practitioners who already have sufficient training and experience in phlebotomy to undergo time-consuming and perhaps inconvenient retraining. The representative of the applicant group on the technical committee acknowledged that grandfathering would also facilitate efficient movement of personnel from one institution to another. This spokesperson stated that one way in which this could be accomplished would be for employers to provide current practitioners with a certificate that they could use to demonstrate to a prospective

new employer what specific training he/she had received in the area of phlebotomy. (Minutes of the Second Meeting of the Technical Committee, August 14, 1991.)

Is the Proposal Cost-Effective?

An employee of the Division of Health Facility Standards of the Department of Health stated that the cost to the Department of developing and implementing the specifics of the proposal would be high because the proposal would require the development of a complete set of distinct rules and regulations for specimen collectors per se. This employee also stated that the proposal would probably require the hiring of additional staff in the Division of Health Facility Standards. This employee stated that lab certification fees would have to be raised to cover the additional costs to the Department of enforcing the terms of the proposal. This employee stated that the costs of such indirect regulation as proposed by NHA might be as costly as direct regulation via the establishment of personnel standards. (Minutes of the Second Meeting of the Technical Committee, August 14, 1991.)

Are There Alternatives to the Proposal?

The committee members discussed such alternatives as licensure of all practitioners, voluntary certification, and the registration of all practitioners. The committee members agreed that neither licensure nor certification were appropriate or cost-effective alternatives for the occupation in question. Both would require educational processes, examinations, and administrative mechanisms that are unjustifiably costly. There was doubt that certification would even address the legal problems that generated the review in the first place since it focuses on title protection and does not address the question of who can or cannot perform a given set of functions. The committee members recognized that registration would address the legal problems raised by the Attorney General's ruling,

but were concerned that even this level of direct regulation of phlebotomy practitioners would be more costly and cumbersome than necessary. The committee members were informed that registration fees could range from $20 to $50 per practitioner. The committee members were also informed that given the fact that phlebotomists are not highly paid professionals these fees would have to be paid by their employers, and that in all likelihood, these costs would in turn be passed on to the public in the form of higher health care costs. (Minutes of the Second Meeting of the Technical Committee, August 14, 1991; and Pages 16-18 of the Transcript of the Public Hearing, September 4, 1991.)

Other options considered by the committee members included the idea of regulating phlebotomy in a manner similar to the way special care practice is regulated. Under this method of regulation would establish a statutory definition for phlebotomy, and if deemed appropriate, specific training standards could be established in statute as well. The committee members were informed that the problem with this option is that it does not address that portion of the Attorney General's ruling which states that phlebotomy is a nondelegable function of the practice of medicine and surgery. Another option discussed is to include all phlebotomists under the term "qualified technologist." The committee members were informed that there currently is no definition in Nebraska law that defines what constitutes a "qualified technologist." Another option that was discussed is the idea of exempting all phlebotomy functions from the practice of medicine. The committee members were informed that this would require a statutory change in the medical practice act. (Minutes of the Second Meeting of the Technical Committee, August 14, 1991.)

As the review progressed, the committee members came to regard the latter option as the most cost-effective means of dealing with the legal problem raised by the Attorney General's ruling on phlebotomy.

COMMITTEE CONCLUSIONS AND RECOMMENDATIONS

At their fourth meeting the committee members met to formulate their recommendations on the proposal. At this meeting the representative of the applicant group on the technical committee requested that the committee members "table" the NHA proposal, and substitute the following idea to deal with the problems posed by the ruling of the Attorney General on phlebotomy practice in Nebraska:

> To recommend to the Board of Health and the Director of Health that the practice of phlebotomy be exempted from the Medical Practice Act. Specifically we recommend that Nebraska Revised Statute 71-1,103 be amended to add to the list of persons who are excepted from the definition of the unauthorized practice of medicine. We concur with the Nebraska Medical Association that the language should be reflected as follows:
>
> > ". . .persons obtaining blood specimens while working under the direction of a physician or registered nurse."
>
> We would further recommend that no additional regulation of the practice be established due to the lack of evidence that unregulated practice is clearly endangering the health, safety, or welfare of the public. (Memorandum to the committee members from John Roberts of the Nebraska Hospital Association, September 30, 1991.)

Concerns were expressed about the reference to "direction of a physician or registered nurse" in the new proposal by some committee members. Some committee members wanted a more definitive statement as to what constitutes "direction." Other committee members were concerned that the wording of this new proposal would mean that only RNs and MDs would have the right to supervise phlebotomists. These committee members felt that non-MD lab directors and physician assistants need to be included on any list of acceptable supervisors for phlebotomists. Some members of the audience expressed the concern that this idea would have an adverse impact on such public health programs as cholesterol screening since these programs

frequently do not have either MDs or RNs to supervise the drawing of blood. (Minutes of the Fourth Meeting of the Technical Committee, September 30, 1991.)

One committee member stated that a facility could employ MDs or RNs as consultants in order to satisfy the above-mentioned supervisory requirement. (Minutes of the Fourth Meeting of the Technical Committee, September 30, 1991.)

Concern was expressed by some committee members that such specific professions as Medical Technology and Respiratory Therapy were not specifically exempted by name in the new proposal. Other committee members stated that the committee should not attempt to develop a laundry list of acceptable professions, and that the best way for RRTs and MTs to address these concerns would be to include language in their regulatory statutes which specifically protects their right to draw blood. (Minutes of the Fourth Meeting of the Technical Committee, September 30, 1991.)

Some committee members felt that the committee should make specific recommendations pertinent to the drawing of blood in DWI cases, and make a recommendation that would give the Department the authority to define what constitutes a "qualified technician." Other committee members felt that the best way to handle DWI issues would be to recommend that the new NHA proposal be applied to all instances wherein blood is drawn for DWI purposes. Concern was expressed that defining "qualified technician" might place some phlebotomists in the position of being required to testify in court in DWI cases. (Minutes of the Fourth Meeting of the Technical Committee, September 30, 1991.)

The committee members unanimously approved a motion by the applicants that tabled the NHA's original proposal, and then unanimously approved another motion which substituted the new NHA proposal to exempt the practice

of phlebotomy from the practice of medicine for their original proposal. The committee members then approved a third motion by the representative of the NMA on the committee that recommended that the idea contained in the new NHA proposal be applied to all DWI cases where blood is drawn for purposes of ascertaining alcohol content. (Minutes of the Fourth Meeting of the Technical Committee, September 30, 1991.)

By these actions the committee members recommended that the original NHA proposal be tabled, and recommended approval of the new NHA proposal to exempt the practice of phlebotomy from the practice of medicine.

OVERVIEW OF COMMITTEE PROCEEDINGS

The members of the Phlebotomy Services Technical Review Committee first convened on June 17, 1991 in Lincoln at the Nebraska State Office Building. At this meeting, credentialing review staff described the duties and responsibilities of the committee under the credentialing review process. Staff discussed the charge to the committee, the four criteria of the Nebraska Regulation of Health Professions Act, and other procedural aspects of conducting a successful review of a credentialing proposal.

The second meeting of the committee was held on August 14, 1991 in Lincoln in the State Office Building. After studying the proposal and other relevant materials compiled by staff and submitted by interested parties between the meetings, the committee members formulated a set of questions and issues they felt needed to be addressed at the public hearing. Contained within these questions and issues were specific requests for information that the committee members felt was needed before any recommendations could be made.

The committee convened on September 4, 1991 in Lincoln, in the State Office Building for the public hearing. The applicants and other testifiers were given the opportunity to express their views on the proposal and the questions raised by the committee at their second meeting. Interested parties were given ten days to submit final comments to the committee.

The committee met for the fourth meeting on September 30, 1991 in Lincoln in the State Office Building. At this meeting the committee members approved a motion by John Roberts of the Nebraska Hospital Association and seconded by Dr. Donald Dynek that the original proposal be tabled.

Voting aye were Ament, Dull, Dynek, Gradwohl, Roberts, Wyrens, and Wempe. There were no nay votes or abstentions.

John Roberts then moved that the committee members substitute the following statement that would recommend to the:

> Nebraska Board of Health and the Director of Health that the practice of phlebotomy be exempted from the Medical Practice Act. Specifically, we recommend that Nebraska Revised Statute 71-1,103 be amended to add to the list of persons who are excepted from the definition of the unauthorized practice of medicine. We concur with the Nebraska Medical Association that the language should be reflected as follows, ". . . persons obtaining blood specimens while working under the direction of a physician or registered nurse." (Memorandum to the committee members from John Roberts of the Nebraska Hospital Association, September 30, 1991. These comments from this memo comprised that portion of the motion made by Mr. Roberts and seconded by Dr. Dynek that defined the new NHA proposal.)

Dr. Dynek seconded the motion. Voting aye were Ament, Dull, Dynek, Gradwohl, Roberts, Wyrens, and Wempe. There were no nay votes or abstentions.

Dr. Dynek moved that the committee recommend that the new language proposed by John Roberts for statute 71-1,103 in his September 30, 1991 memo to the committee members be applied to all DWI cases wherein blood is drawn to ascertain alcohol content. John Gradwohl seconded the motion. Voting aye were Dull, Dynek, Gradwohl, Roberts, Wyrens, and Wempe. Voting nay was Ament. There were no abstentions.

By these votes the committee members agreed to table the applicants' proposal, and to recommend approval of the new NHA proposal that would exempt the practice of phlebotomy from the practice of medicine.